# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

in the matter of the PATENT application of

Inventor Wilson Smart et al

Title SILICON LANCET DEVICE

AND METHOD OF CONSTRUCTION

Ser.No. 09/817,567 Filed March 26, 2001

Patent Examiner unassigned Art Group Unit 1746

Commissioner for Patents Washington D.C. 20231

October 19, 2001

PRELIMINARY AMENDMENT
SUBMISSION OF SUBSTITUTE FORMAL DRAWING
CLEAN COPY OF WRITTEN DESCRIPTION
(under 37 CFR 1.121)

Sir;

This paper is submitted as a Preliminary Amendment to the above identified recently filed application. Please amend this application as follows:

## IN THE TITLE:

Page 1, line 1, DELETE "AND METHOD OF CONSTRUCTION"

#### IN THE DETAILED DESCRIPTION:

Page 1, line 13, AFTER "beveled edges"

insert --forming the point--.

Page 1, line 15, AFTER "trauma" ADD --.--.

Page 1, lines 17-18, CHANGE

""Microfabrication techniques for integrated sensors and microsystems," TO

-- "Microfabrication Techniques for Integrated Sensors and Microsystems", --.

Page 1, line 25, CHANGE

""Silicon processed microneedles,""

TO -- "Silicon Processed Microneedles", --.

Page 1, line 30, AFTER "period" ADD --.-.

(Kum 13 Sil.Lan) Page 1 PreAm Pap 3 SN 817,567

4

PECEIVED TO 1700

- Page 2, line 4, AFTER "SOI"

  INSERT -- (silicon on insulator) --.
- Page 2, line 15, DELETE "and method for"
- Page 2, line 16, DELETE "the construction thereof"
- Page 2, line 17, AFTER "human hair"

  INSERT -- (80 micrometers) --.
- Page 3, line 7, AFTER "process." DELETE -- .--.
- Page 4, lines 25-26, DELETE
  "in accordance with the present invention".
- Page 4, line 26, AFTER "wafer" ADD --12a--.
- Page 4, lines 29-30, DELETE
  "in accordance with the present invention".
- Page 4, line 30, AFTER "film" ADD --14b--.
- Page 5, lines 2-3, DELETE
  "in accordance with the present invention".
- Page 5, line 4, AFTER "photoresist" ADD --16c--.
- Page 5, lines 6-7, DELETE
  "in accordance with the present invention".
- Page 5, line 7, AFTER "film" ADD --16d--.
- Page 5, lines 10-11, DELETE

  "in accordance with the present invention".
- Page 5, lines 14-15, DELETE

  "in accordance with the present invention".
- Page 5, line 15, CHANGE "and" TO --to--.
- Page 5, lines 18-19, DELETE
  "in accordance with the present invention".
- Page 5, line 19, AFTER "coat" ADD --18g--.
- Page 5, lines 22-23, DELETE
  "in accordance with the present invention".
- Page 5, line 24, AFTER "etching process"

  CHANGE "," TO --;--.
- Page 5, line 25, DELETE "and"
- Page 5, lines 27-28, DELETE
  "in accordance with the present invention".

- Page 5, line 29, AFTER "device with"

  ADD --penetrating portion 12p and--.
- Page 5, line 29, AFTER "covered base"

  CHANGE "." TO --portion 12i;--.
- Page 5, line 32, CHANGE "lancet."

  TO --lancet in the finger or arm;--.
- Page 5, line 33, ADD the following three paragraphs:
- FIG. 3A is a top view of silicon device 30i showing base end 30b and penetration end 30p;
- FIG. 3B is a side view of silicon device 30i of FIG. 3A showing silicon nitride film 34; and
- FIG. 3C is an end view of silicon device 30i of FIG. 3A showing a rectangular cross-section.
  - Page 6, lines 2, CHANGE "FIGS." TO --FIG.s--
  - Page 6, lines 2-3, CHANGE "basically comprises"
    TO --is--.
  - Page 6, line 3, AFTER "at 10i"

    ADD -- (see FIG. 11) --.
  - Page 7, line 1, CHANGE "Basically, the lancet"
    TO --Lancet--.
  - Page 7, line 1, AFTER "short probe" ADD --12p--.
  - Page 7, line 13, CHANGE "FIGS. 1-9"
    TO --FIG.s 1A-11--
  - Page 7, line 14, CHANGE "FIG. 1"

    TO --FIG 1A--.
- Page 8, line 32, add the following single paragraph concerning lancet device Claims 24-30.

MICROLANCET DEVICE - FIG.s 3A 3B and 3C
Disposable microlancet device 30i (see FIG. 3A) may
be employed for obtaining a blood sample through the skin

of a subject. The device is formed by an elongated single crystal silicon substrate 32a having base end 30b and penetration end 30p. Base portion 32b formed at the base end of the silicon substrate permits the device to be retained during penetration and sampling. Penetration portion 32p formed at the penetration end terminates in a sharp point with smooth continuous cutting profile. The smooth profile permits easy piercing and penetration of the skin in order to obtain a blood sample while inflicting minimum pain on the subject. The penetration portion has a thickness cross-section dimension "T" (see FIG.s 3B and 3C) and a width cross-section dimension "W" (see FIG.s 3A and 3C). The cross-section may be any suitable shape such as rhombic or rectangular as shown in FIG. 3C. The thickness dimension T of the base portion may extend from about 50 micrometers to about 250 micrometers excluding the sharp point. The width dimension W of the base portion may extend from about 50 micrometers to about 250 micrometers excluding the point. At least one of these dimensions may taper toward the penetration end to form the sharp point (see FIG. 3A). The silicon substrate may have a length dimension "L" (see FIG. 3B) of from about 1 millimeter to about 3 millimeters. Silicon nitride film 34 may extend of over at least part of the base portion.

# IN THE FIGURES

Replace original Figures 1A-1I (one sheet of drawing) with replacement Figures 1A-1I (one sheet of drawing). Replace original Figure 2 (one sheet of drawing) with replacement Figure 2 (one sheet of drawing). Add new Figures 3A-3C (one sheet of drawing) showing the lancet device. The above changes to the figures are noted in the accompanying Draftsperson's Letter.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE \* \* \* the matter of the PATENT application of

Inventor Wilson Smart et al

Title

SILICON LANCET DEVICE

AND METHOD OF CONSTRUCTION

Ser.No.

09/817,567

Filed

March 26, 2001

Patent Examiner

unassigned

Art Group Unit

1746

Commissioner for Patents

Washington D.C. 20231

October 19, 2001

## FEE TRANSMITTAL SHEET FOR PRELIMINARY AMENDMENT

Transmitted herewith is a Preliminary Amendment (Paper No 2) in this patent application.

Small entity status under 37 CFR §1.9 and §1.27 has been established by a verified statement previously submitted. No additional fee is required.

CLAIMS HIGHEST REMAINING NUMBER AFTER PREVIOUSLY PRESENT ADDITIONAL AMENDMENT PAID FOR EXTRA RATE FEE TOTAL 07 23 00 \$09.00 \$000.00 CLAIMS INDEP 02 \$40.00 \$000.00 CLAIMS ADDITIONAL FEE \$000.00 FOR CLAIMS

Please charge Deposit Account No. x x x x in the amount of  $x \times x \times A$  duplicate copy of this sheet is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No.  $x \times x \times x$ .

 $\Pi$ A check in the amount of x x x x to cover the above fee is enclosed.

Wilson Smart

Applicant (510) 476-0956

(Kum 13 Sil.Lan)